



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/462,637	06/06/95	GREENE	J 1488.0710001

HM11/0603
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EXAMINER

ART UNIT PAPER NUMBER

1646

24

DATE MAILED: 06/03/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3-13-98 (Paper No. 22)

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 21-29, 31-34 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 31 is/are allowed.
- ☒ Claim(s) 32-34 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-946.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

PTOL-32a

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Response to Amendment

1. The finality of the rejection of the last Office action is withdrawn in view of the new rejection under 35 U.S.C. 112, second paragraph set forth below.
2. Amendment filed 13 March 1998, Paper No. 22, has been entered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments filed 13 March 1998, Paper No. 22 have been fully considered but they are not found persuasive.
5. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646 (formerly 1812).

Information Disclosure Statement

6. The previous office action indicated that the information disclosure statements filed 23 January 1997(Paper No. 13) and 18

April 1997 (Paper No. 15) do not comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because references AR7, AS7, AS8, AT8, AR9, AS2, AR10, AS10, AT10, and AR11 are not journals, patents, or publications.

Applicants argue that there is no requirement for the "information" to be in a particular form. However, unlike journal publications, the copy of the sequence listing contains sequence comparisons without an explanation of the relevance of the disclosure. It is suggested that a submission of a clear and concise explanation of the references would further reveal the significance of the references. Furthermore, AS10, AT10, and AR11, are search reports which are part of the foreign patent documents. It is suggested that the full PCT report including the patent and the attached search report be listed under the heading of the foreign patent documents. Finally, since the previous Form 1449 has crossed out the reference information, it is suggested that a new form would prevent any loss of information due to the previous crossing out of the references not considered. The references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any

missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Oath/Declaration

7. The Declaration under 37 CFR 1.132 filed 13 March 1998 (Paper No. 22) is sufficient to overcome the rejection of claims 21-35 based upon new matter rejection under 35 U.S.C. 112, first paragraph set forth in last office action.

Specification

8. The amendment filed 28 March 1997 (Paper No. 17) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

Amendment to page 6, lines 26-27, which changes "39%" to "about 27%", "46%" to "about 43%", and "an 88 amino acid stretch" to "the entire length of the proteins" is not supported by the specification. At the time of the invention one skilled in the art could not determine the metes and bounds of the term "%

identity" for the reason set forth in the 35 U.S.C. 112, second paragraph below. Without the disclosure of the meaning of "% identity", one skilled in the art could not determine the changes to the specification on page 6, lines 26-27, discussed immediately above.

Amendment on page 1, for priority information, recites "which is relied upon and incorporated by reference in its entirety" which is not supported by the specification as filed. At the time of filing of the application, the specification did not incorporate the PCT/US95/03216.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 112

9. Claims 21-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 recites "amino acid -20 to 380 of SEQ ID NO:2"; the examiner could not find support in the specification for the concept of a polynucleotide with such claim limitations. Claims 22-29 are dependent on claim 21.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 21-29 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-29 and 32-34 are indefinite because instructions or an algorithm for determining percent sequence identity is missing from the specification. Claims 21-29 and 32-34 use "identity" in terms of percentage. The specification fails to clearly set forth the algorithm and the parameters within the algorithm which would be necessary to do the percent identity calculations. The state of the art is such that one skilled in the art cannot determine what the meaning of the term "identity" is without a precise algorithm with parameters i.e. "scoring rules"(George et al.(V), page 130, right column, top paragraph, is cited as of interest to the applicant). For example, consider two hypothetical sequences acgtac and acac. These can be compared in any of four ways, yielding four different percent identity results.

acgtac 4/6 = 67% acgtac 2/6 = 33%

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ac--ac 4/4 = 100% acac 2/4 = 50%

Thus, a specific definition of "identity" must be provided taking into considerations such variables as: complete vs partial sequence, gap distances, as well as other parameters of the algorithm. Claims 22-29 and 33-34 are dependent on claims 21 or 32.

12. Claim 31 is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MDP
Michael D. Pak
1646
26 May 1998

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800